Standard Operating Procedures for Sponsorship Approval of CTIMPs

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Author: Antony Walsh Designation: RES Research Governance Officer	Signature	Date 25 August 2020

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: SSC Chair

2. Introduction

2.1 The University of Sussex, through its Code of Practice for Research, is committed to promoting and upholding the highest quality academic, professional and ethical standards in all its activities and seeks to foster a culture of professional integrity.

Good Clinical Practice (GCP)

2.2 The University expects that all clinical research involving human participants is undertaken in line with the principles of GCP.

2.3 Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design and conduct of clinical research involving humans. GCP is a set of core principles, which applies to all clinical investigations that could affect the safety and wellbeing of human participants. GCP is internationally recognised as best practice and compliance (including up to date training) and is a legal obligation in the UK/Europe for all trials of investigational medicinal products. GCP was developed by the regulatory authorities represented in the Tripartite International Conference on Harmonisation and provides international assurance that:

(i) Data and reported results of clinical investigations are credible and accurate, and;
(ii) The rights, safety, and wellbeing of the trial subjects are the most important considerations and should prevail over interests of science and society

3. Responsibilities

Chief Investigator

3.1 The Chief Investigator (CI) is responsible for making a request to the University of Sussex to act as Sponsor and fulfilling the terms of the 'Conditions of Sponsorship Agreement' issued when the study has been formally accepted for Sponsorship. The CI may delegate the activities described in this SOP to sufficiently experienced members of the research team or Professional Support Services (e.g. the Joint Clinical Research Office (JCRO) or Clinical Trials Unit), however the final responsibility for ensuring compliance with the SOP' Sf3(s)1 **S** e sor5 (o)-6.7 (5 (exp)5.)-1.3 (p)2.3 (h)05 (o)e 5 (exp)5.9 (e)4.9 (-3 (fin)2

- The project is related to an academic qualification and the University is likely to be able to provide sponsorship on the basis of being able to provide acceptable oversight and the management of appropriate levels of risk in keeping with the institution's status as an educational establishment

Who should request Sponsorship ?

4.3 It is the responsibility of the CI on a project to request Sponsorship. However, it is recognised that this responsibility may be delegated to another member of the research team with sufficient knowledge of the research activity.

How and When to request Sponsorship?

Prior to submission of an application for funding – Application for 'Sponsorship in Principle' for a CTIMP

4.4 The CI should liaise with University Research Governance Officer as early as possible in the study planning process to discuss potential sponsorship ('sponsorship in principle'). The CI is expected to formally request Sponsorship once funding for a research project has been confirmed.

4.5 In circumstances where the funding body requires confirmation of Sponsorship prior to submission of the funding application, the CI should contact the Research Governance Officer in Research and Enterprise Services (researchsponsorship@sussex.ac.uk).

4.6 The following should be submitted for the purposes of: 'sponsorship in principle'

a) Confirmation of who the CI is and a copy of their CV (updated within the last 2 years)
b) Confirmation of the clinical trial phase for the trial
c) Confirmation that the proposed study is classed as a CTIMP if applicable
d) An outline trial protocol to enable the sponsor to risk assess the trial and categorise the

l) Confirmation of vendors likely to be used in the trial and confirmation (at least in principle) of what activity they will be providing (e.g. CTU, IMP distribution, randomisation service, GMP facility,
m) Laboratories) – each vendor to be listed separately
n) Proposed archiving arrangements and costs

4.8 The University will require the following information about the proposed CTU who will be supporting the Trial:

a) A complete list of activities the CTU has agreed to provide for the trial (plea03 TRe3eny<</MCID9ws4

- Consent form for each group of participants involved in the study with a new version number and date in the footer of the document
- Recruitment materials: emails / posters / letter of approach to for e.g. GPs, gatekeepers; interview schedules and topic guides
- Any validated questionnaires to be used
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GP	General Practitioner
HRA	Health Research Authority
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IMP	Investigational or Medicinal Product
ISF	Investigative Site File
IRAS	Integrated Research Application System
JCRO	Joint Clinical Research Office
MHRA	Medicine and Healthcare Products Regulatory Agency
NHS	National Health Service
PI	Principal Investigator
PIS	Patient Information Sheet
R&D	Research and Development
REC	Research Ethics Committee
REIGO	Research Ethics and Integrity Office
SOECAT	Schedule of Events Cost Attribution Template
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reactions)

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments http://www.legislation.gov.uk/uksi/2004/1031/contents/made

Is my study research? Medical Research Council - http://www.hradecisiontools.org.uk/research/

Is it a Clinical Trial of a Medicinal Product? Medicines and Healthcare Regulatory Agency (MHRA) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/317952/Algorithm.pdf

NIHR Clinical Trials Toolkit -

APPENDIX A: Conditions of Sponsorship Agreement

Conditions of Sponsorship Agreement

The University of Sussex will act as Sponsor, as defined by the Medicines for Human Use (Clinical Trial) Regulations 2004 and the UK Policy Framework for Health and Social Care Research (2017) for the above research project provided that the Chief Investigator adheres to the following conditions of sponsorship:

a) HRA approval has been received for the study.

b) Confirmation of Capacity & Capability is received from relevant NHS Trusts before any patients or participants are recruited.

c) The CI (Chief Investigator) and members of the research team will comply with all applicable regulations; including the principles from the UK Policy Framework for Health and Social Care Research (2017) the Medicines for Human Use (Clinical Trials) regulations 2004 and subsequent amendments (if a CTIMP), ICH GCP, the Data Protection Act 1998, the Human Tissue Act 2004 and any other relevant guidance and/or legislation.

d) The CI and members of the research team will comply with the University's Code of Practice for Research.

e) All research team members are appropriately GCP trained throughout the duration of the study.

f) Ensuring that the study is registered on an appropriate registry prior to recruitment of the first patient if applicable.

g) Ensuring that the clinical trial data is generated, documented and reported in accordance with the protocol, GCP and regulatory requirements.

h) A delegation log is completed and kept up to date throughout the duration of the trial.

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APPENDIX B: University Sponsorship Application Document checklist

** Please ensure that you download the latest copy from
http://www.sussex.ac.uk/staff/rese